

K081118

MAY - 2 2008

## **SECTION 9**

### **510(K) SUMMARY**

**MR-BI320-PA 1.5T**

**Date of Summary Preparation:** April 4, 2008

**This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.**

**1. General Information**

**Importer/Distributor**

**Name and Address**

Siemens Medical Solutions, Inc.  
51 Valley Stream Parkway  
Malvern, PA 19355

**Establishment Registration Number**

2240869

**Manufacturing Site**

**Name and Address**

Noras MRI products GmbH  
Leibnizstrasse 4  
97204 Höchberg  
Germany

**Establishment Registration Number**

Establishment Registration 3004929307

Owner/Operator 9071737

**2. Contact Person**

Martin Hempel  
 Noras Röntgen- und Medizintechnik GmbH  
 Leibnizstr. 4  
 97204 Höchberg, Germany

**Telephone:** (+49) 931/29927-29

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**Email Address:** martin.hempel@noras.de

**3. Device Name and Classification**

<b>Trade Name:</b>	<b>Noras Patient Rest MR BI320 1.5T</b>
<b>Common Name:</b>	<b>MR-BI320-PA 1.5T</b>
<b>Classification Name:</b>	Magnetic Resonance Diagnostic Device
<b>Classification Panel:</b>	Radiology
<b>CFR Number:</b>	21 CFR § 892.1000
<b>Device Class:</b>	II
<b>Product Code:</b>	90MOS and LNH

**4. Device Description**

The MR-BI320-PA 1.5T is a patient rest with a immobilization- and biopsy unit and a 4-channel phased array receive only coil.

The coil is factory pre-tuned to the fixed load and no further tuning or matching is required for the patient.

The coil is divided into two spherical parts. Each half contains a 2 channel receive only array.

The upper coil is connected with a cable and a plug with the insertion coil. The insertion plate coil is connected to the scanner with a cable connection.

The insertion plate coil is designed to enable insertion of immobilization and biopsy system and is inserted into the patient rest.

The upper coil (patient pad coil) serves as a positioning pad for the patient at the same time.

## 5. Intended Use

The intended use of the Noras MR-BI320-PA 1.5T is, in conjunction with a Magnetic Resonance Scanner, the MR examination of the female breast. It is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures of the female breast. When interpreted by a trained physician, these images provide information that can be useful in determining diagnosis.

The included Breast Biopsy Unit BI160-2 permits MR guided breast biopsy and wire localization of lesions that can be performed by a trained physician.

## 6. Substantial Equivalence

Noras believes that, within the meaning of the Safe Medical Devices Act of 1990, the 4-channel phased array Breast Coil 1.5T of the MR-BI320-PA 1.5T is substantially equivalent to the following coil:

Coil Name	Premarket Notification	Clearance Date
MRI Devices Corporation (Now Known as Invivo Corporation)  Breast Array Coil  Model OBC-63 ME	K002602	September 08, 2000

The immobilization and biopsy unit BI160-2 is a redesigned model due to the dimensions of the patient rest of the following Noras Immobilization and Biopsy units.

Immobilization and Biopsy Unit	Pemarket Notification	Clearance Date
Noras Immobilization and Biopsy Unit Model BI160	K010570	April 09, 2001
Noras Immobilization and Biopsy Unit Model BI160-PA	K052987	November 08, 2005

The immobilization and biopsy unit BI320-DC is a redesigned model of the predicate devices mentioned before to achieve a cranial access to both breast at one time.

Immobilization and Biopsy Unit	Premarket Notification	Clearance Date
Noras Immobilization and Biopsy Unit Model BI160	K010570	April 09, 2001
Noras Immobilization and Biopsy Unit Model BI160-PA	K052987	November 08, 2005

#### **7. Summary of Technological Characteristics of the Principal Device as Compared with the predicate Devices**

The MRI (now Invivo) 4 channel OBC (Open Breast Coil) has been designed to examine the female breast. The patient lies in prone position on top of the coil, which is designed as a patient rest. Cushions complete the set for a comfortable patient positioning.

In combination with the Noras BI160 the immobilization of the breast it is achieved to avoid moving artifacts during the scan. A biopsy can be taken by using the post and pillar or grid localization system to guide the needle under MR control to the lesion.

The Noras BI160-PA is a patient rest, including a immobilization and biopsy unit without an integrated coil. To get MR Images it is mandatory to use the loop coils of the MRT System manufacturer. The approach of this new product was, to give the physician a more comfortable access to the region of interest in the female breast (medial, cranial and lateral) and even the higher, alary near positions.

The Noras MR-BI320-PA 1.5T comes along with a 4 channel breast coil for 1.5T Siemens MRT systems (Avanto, Espree, Tim Symphony, Sonata and Symphony). The dedicated 4 channel 1.5T breast coil enables a MR guided biopsy under comparable picture quality as the MRI OBC coil (see Appendix C Test Protocols, due to Standard NEMA MS 6-2001) and the advantages on the intervention side of the Noras BI160-PA.

Today it becomes more and more common to use vacuum biopsy systems to get the tissue samples out of the region of interest for examination in the laboratory. Therefore different interfaces or adapters have been developed for the Noras biopsy units. These accessories are equal to the standard parts, with the exception of the hole diameters.

## 8. General Safety and Effectiveness Concerns

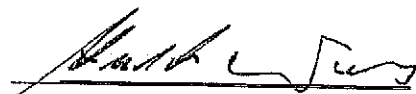
The complete system MR-BI320-PA 1.5T will conform the harmonized standard of IEC 60601-1 3<sup>rd</sup> edition, Medical electrical equipment - General requirements for basic safety and essential performance.

The MR-BI320-PA 1.5T coil will conform to the FDA recognized NEMA Standards for the measurement of performance and safety parameters and the IEC standards for safety issues with the Magnetic Resonance Imaging Devices, IEC 60601-2-33: 2002. This will assure that the performance of this device can be considered safe and effective when used with the currently available MAGNETOM 1.5T systems.

All tests are performed on the Siemens Avanto. This is the most critical engine for safety and performance of the Siemens 1.5T series. Passing these tests gives the Siemens approval for the complete 1.5T series.

## 9. Conclusion as to Substantial Equivalence

Noras believes that, within the definition of the Safe Medical Devices Act of 1990, the Noras 4-channel phased array Breast coil 1.5T with its patient rest and immobilization and biopsy units is substantially equivalent to the predicate devices listed above.



Hubert Noras

President

April 4, 2008



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAY - 2 2008**

Noras MRI Products GmbH  
% Mr. Stefan Preiss  
Responsible Third Party Official  
TÜV SÜD America  
1775 Old Hwy 8 NW, Ste 104  
NEW BRIGHTON MN 55112-1891

Re: K081118

Trade/Device Name: Noras MR-BI320-PA 1.5T  
Regulation Number: 21 CFR 892.1000  
Regulation Name: Magnetic resonance diagnostic device  
Regulatory Class: II  
Product Code: MOS  
Dated: April 16, 2008  
Received: April 21, 2008

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

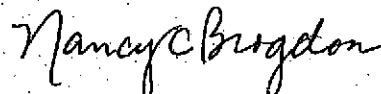
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: Noras MR-BI320-PA 1.5T

Indications for Use:

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Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal and  
Radiological Devices  
510(k) Number K081118

(Posted November 13, 2003)